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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,816	03/31/2000	Gavin Paul Vinson	BKY 2 040 -1- 1- 1	3602

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	09/540,816	VINSON ET AL.
Examiner	Art Unit	
Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 February 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 18-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 19 and 21 is/are allowed.

6) Claim(s) 18 and 20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. 08/624,374.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

1. The amendment filed 2/10/2003 (paper no 12) is acknowledged and entered into the record. Accordingly, claims 1-7, 11, 14-17 are canceled without prejudice or disclaimer, claims 20 and 21 are newly added.
2. Therefore claims 18-21 are pending and examined on the record.

***Claim Rejections Withdrawn - 35 USC § 112, 2<sup>nd</sup> paragraph***

3. The rejections of claims 14-17 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite withdrawn in view of the cancellation of claims.

***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejections of claims 4 and 19 under 35 USC 112, 1<sup>st</sup> paragraph for lacking proper written description is withdrawn in view of the cancellation of claims or in view of the amendments provided.

***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

5. The rejections of claims 1-3, 5-6, 11, and 14-17 under 35 USC 112, 1<sup>st</sup> paragraph for lacking enablement is withdrawn in view of the cancellation of claims.

***Claim Rejections Withdrawn - 35 USC § 102***

6. The rejections of claims 1-7, 11, and 18 under 35 USC 102 as being anticipated is withdrawn in view of the cancellation of claims.

***Double Patenting***

7. The rejection of claims 1-7 under the judicially created doctrine of obviousness type double patenting is withdrawn in view of the cancellation of the claims.

## **NEW ARGUMENTS**

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth the antibody produced by a hybridoma cell line deposited at the European Collection of Animal Cell Cultures under Accession number 930720117 fragments and conjugates of antibodies derived from this cell line and is therefore not commensurate in scope to claims that read on any and all antibodies that bind to the angiotensin II AT1 subtype receptor, wherein the antibody is conjugated to a detectable label. The specification is devoid of teaching any other antibody that is capable of binding to angiotensin II AT1 subtype, as such the specification has not provided enough indication to one of skill in the art at the time of the invention that the applicant was indeed in possession of the claimed generic antibody and its conjugates that binds to the angiotensin II AT1 subtype receptor. In order for the applicant to be entitled to the broad genus of anti-angiotensin II AT1 subtype receptor antibodies, the applicant must be able to show a representative number of antibodies that bid specifically to the

protein. Because there is a lack of any such disclosure and because the specification has only outlined the use and production of a single antibody to angiotensin II AT1 subtype, the specification has not exemplified to one of skill that the applicant was in possession of any and all antibodies nor any kits that comprise any and all antibodies whether bound or unbound to detectable labels.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 18 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Reilly TM (EP 273453). Claims are drawn to a diagnostic kit comprising a monoclonal antibody attached to a detectable label. Reilly TM disclose a monoclonal antibody that is specific for angiotensin II and further teaches that such antibodies can be attached to detectable labels (see claims 1-6 and 17). Because the instantly claimed antibody cannot be distinguished over the antibody disclosed in the prior art, and because the patent office does not have the facilities to distinguish the differences between the antibodies, in the absence of evidence to the contrary the antibodies taught in the prior art reads on the instantly claimed antibody and conjugates claimed.

***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
May 5, 2003

*[Signature]*  
PRIMARY EXAMINER  
AL R. SALMI